

## Chapter 5

# Medicare Expenditures for Immunosuppressive Drug Therapy

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# Medicare Expenditures for Immunosuppressive Drug Therapy

This chapter commences with a baseline estimate of current spending for outpatient immunosuppressive drugs in the United States and under the Medicare program. The chapter then describes factors influencing drug costs, the potential pool of patients requiring post-transplant immunosuppressive drugs, and overall future Medicare expenditures.

## CURRENT EXPENDITURES

Medicare does not currently play a major role in financing post-transplant immunosuppressive therapy. Medicare covers and pays for immunosuppressive drugs for only an estimated 19 percent of Medicare-covered functioning graft recipients (table 17). Likewise, Medicare pays the immunosuppressive drug costs for only about 13 percent of the U.S. total number of living, functioning graft patients. This small proportion is due largely to the 1-year limit on coverage of immunosuppressives.

Another element of financing that influences these percentages is the mandatory requirement that Medicare be the secondary payer for the first 18 months of a patient's eligibility under the End-Stage Renal Disease (ESRD) Program.<sup>1</sup> In other words, even though an ESRD patient is entitled to Medicare coverage once determined eligible for Medicare benefits, Medicare will pay for covered services provided these beneficiaries only after any existing private insurance policies have paid. Approximately 37 to 67 percent of Medicare-covered kidney transplant recipients have private insurance during this period (see ch. 4).<sup>2</sup> Therefore, even within the 1-year coverage period for outpatient immunosuppressives, Medicare is not paying for the drugs administered to these ESRD kidney transplant recipients because of the mandatory secondary payer requirement.

The Office of Technology Assessment (OTA) estimates that national spending for outpatient immunosuppressive agents was between \$185 and \$280 million in 1988 (table 18). Medicare-related expenditures, including all beneficiary liabilities, were an estimated \$20 to \$30 million, or nearly 11

percent of total U.S. spending in this area (7,17). These estimates are based on the assumption that all functioning graft patients are on a cyclosporine protocol costing between \$4,000 to \$6,000 per year (see ch. 3).<sup>3</sup> Because of patient copayments, actual Medicare program outlays would have been somewhat less than 80 percent of the \$24 to \$36 million, or under roughly \$20 to \$30 million.

These estimates are a reasonable first approximation of national and Medicare expenditures for

**Table 17—Estimated Number of Transplant Recipients Receiving Medicare Payment of Immunosuppressive Drugs, 1988**

Graft type	Number <sup>a</sup>	Proportion with Medicare drug payment as a percent of:	
		All Medicare-covered transplant recipients	All U.S. transplant recipients
Kidney . . . . .	5,850 <sup>b</sup>	1970	15%
Heart . . . . .	95	45	3
Liver . . . . .	5 <sup>c</sup>	48	<1
Heart/lung . . . . .	0	—	—
Lung . . . . .	0	—	—
Pancreas . . . . .	0	.	—
Bone marrow . . . . .	30	55	1
Total . . . . .	5,980	19	13

<sup>1</sup>Since 1982, Medicare has been the mandatory secondary payer for ESRD beneficiaries for the first 12 months of eligibility. A provision in the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) extended this limit to cover the first 18 months of eligibility, effective Jan. 1, 1991.

<sup>2</sup>In contrast, only 3 percent of the working aged have selected Medicare as secondary payer (37).

<sup>3</sup>This assumption should result in an overestimate of expenditures, since a few patients are not on cyclosporine-based protocols.

**Table 18—Estimated U.S. and Medicare Expenditures for Outpatient Immunosuppressive Drug Therapy, 1988**

	Number of recipients with functioning graft	cost of therapy	Total expenditures (in millions) <sup>c</sup>
United States . . . . .	46,605 <sup>b</sup>	\$4,000-\$6,00W	\$185-\$280
Medicare-covered . . . . .	5,98@	\$4,000-\$6,00&	\$24-\$36 <sup>o</sup>

<sup>a</sup>Assumes that 100 percent of functioning graft patients are on cyclosporine drug therapy. This overstates actual expenditures, since some kidney transplant recipients are on traditional therapies with lower costs and a few are not on outpatient immunosuppressive therapy.

<sup>b</sup>See table 11.

<sup>c</sup>See oh. 3.

<sup>o</sup>See table 16.

eIncludes all beneficiary liabilities. Actual program outlays would be lower.

SOURCE: Office of Technology Assessment, 1991.

outpatient immunosuppressive medications in 1988; 1991 expenditures would be somewhat higher, due to the continuing increase in the number of organ transplant procedures. The Medicare figure is a baseline estimate of 1988 expenditures (including beneficiary liabilities). It is based on coverage as set out in current law, under which outpatient immunosuppressive drug coverage is limited to one year, starting with the patient's discharge date from a hospital or designated transplant center after a Medicare-covered organ transplant.

Note that these figures are not estimates of the overall cost of immunosuppressive therapy. They do not, for instance, encompass other services related to immunosuppressive therapy, such as a hospital outpatient visit or physician immunosuppressive drug management services. They also do not account for the costs of drug therapy in organ rejection episodes or the costs of treating side effects caused by immunosuppressive drugs. Other factors that might affect these expenditure estimates include patient behavior, such as noncompliance; variation in patient treatment; and provider prescribing (e.g., conversion from one therapy to another).

## FACTORS INFLUENCING FUTURE EXPENDITURES

The effect of any particular change in Medicare policy regarding immunosuppressives depends in part on a number of outside factors, which can be separated into two groups. The first set of factors affects the cost of the drug product. A second set of factors affects the potential pool of transplant patients receiving Medicare coverage for immunosuppression. Both affect the overall cost of providing this therapy.

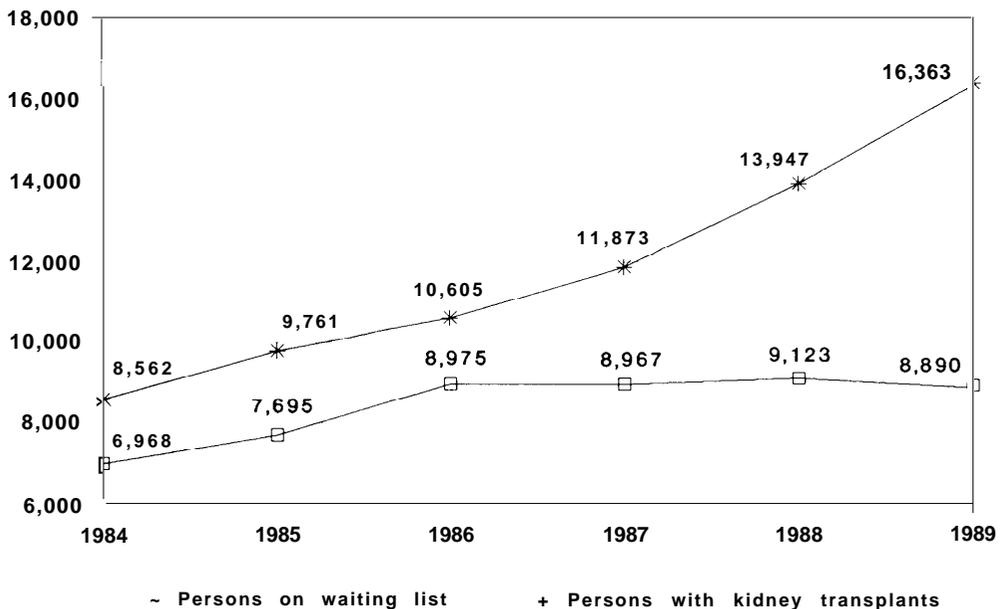
No definitive empirical evidence is available on the precise effect of any one of these factors on current or future Medicare expenditures. Nonetheless, the effects could be substantial. Nearly half of the factors could influence Medicare outlays in the future even if there are no changes in coverage policy. Other factors are issues to consider only if Medicare's policy for coverage of outpatient immunosuppressives is expanded.

### *Changes in the Immunosuppressive Drug Market*

Even without any changes in policy, future Medicare expenditures for outpatient immunosuppressives could be significantly affected by changes in the market. For example, any new products now under development (e.g., the drug FK-506) have the potential to be more costly than cyclosporine when approved for clinical use. Medicare outlays for outpatient immunosuppressives may increase with the use of more costly drugs, even if coverage policy is unchanged from the 1-year coverage limit. Alternatively, a greater choice of drugs and the development of lower-cost protocols could reduce Medicare expenditures.

Other changes in drug pricing could occur when the patent for cyclosporine expires in 1995. After that time, the potential for the availability of less expensive generic drugs also exists. Whether this potential will be realized depends on whether other pharmaceutical manufacturers decide to enter the immunosuppressive market. The extent to which future costs are lower also depends on Sandoz' own reliance on revenues from this drug. Some research suggests that Sandoz may maintain a high price for

Figure 3-U.S. Kidney Transplants Performed, and Persons on Waiting List, 1984-89



SOURCE: Office of Technology Assessment, 1991, based on data provided by the Health Care Financing Administration.

cyclosporine if this product is a major source of revenues to the company (10,50).

Changes in the way existing drugs are used could also affect the cost of therapy and Medicare outlays. For example, the use of OKT-3 as an outpatient prophylactic would tend to increase the cost of outpatient immunosuppressive therapy. Minnesota's antilymphocyte globulin may also be used more widely once it receives approval from the U.S. Food and Drug Administration, although this is more likely to affect inpatient costs than outpatient maintenance expenses.

Innovations and substitutions can have significant and not always consistent consequences for the cost of immunosuppressives. For example, if a new drug is more expensive but reduces the need for adjunct drugs, or reduces rejection and complications-related expenses, it could result in lower treatment costs per patient.

### *Patient Demand and Patient Mix*

It is possible that patient selection for a transplant procedure may be influenced, however indirectly, by the ability of the patient to pay for expensive outpatient therapy following the transplant. To this

extent that this is so, more comprehensive outpatient immunosuppressive drug coverage by Medicare may increase patient demand, either directly or by increasing physician recommendations for transplants.

Despite possible higher demand, the limited supply of suitable organs will continue to constrain the number of transplant procedures performed. Even with existing demand, for example, the number of persons on the waiting list for kidney transplants is much higher than the number of persons transplanted (figure 3). The existing unmet need for donated kidney organs is projected to continue through the decade (18,21). Thus, expanding immunosuppressive coverage may increase the demand for organ transplants, but it will have little effect on the actual number of transplants performed.

Although the number of transplants may not be influenced by Medicare's coverage policy for outpatient immunosuppression, the mix of patients receiving transplants may be affected. The criteria by which one patient is selected over another for a transplant are broad and complex, and inability to pay for drugs in the future would rarely, if ever, be an explicit criterion (30,38). Nonetheless, current

discrepancies due to insurance status and race have been noted in the treatment of patients for kidney failure (30,58). Broader Medicare drug coverage might indirectly improve the equity of access to transplants. If Medicare's coverage limit of 1 year were eliminated, for example, patients who are now unable to afford the expense of these drugs following kidney transplant may be more likely to consider the procedure rather than continue on dialysis. Similarly, transplant centers and physicians may change their evaluation process for selecting transplant candidates.

The implications that changes in patient mix may have for Medicare outlays overall are not easily predicted; expenditures may either increase or decrease depending on the resulting differences in the health status, age, or other characteristics of the new transplant population served. Any effect specifically on Medicare drug expenditures, however, would probably be small.

### *Patient Adherence to Therapy*

Expanded coverage may increase patient adherence to the prescribed drug regimen, resulting in more regular and continued use of the immunosuppressive drugs that the patient requires. The outcome may be fewer episodes of acute organ rejection, fewer hospitalizations, and possibly fewer patients returning to dialysis. Expanding Medicare's coverage policy may thus reduce certain other Medicare expenditures.

Estimating the number of organ rejections that result from nonadherence to therapy, due to a financial inability to obtain drugs, is difficult. On the one hand, the American Society of Transplant Surgeons (ASTS) believes that nearly 47 percent of transplant recipients have difficulty paying for drugs, implying a high potential inability to obtain drugs (4)<sup>4</sup> On the other hand, U.S. Health Care Financing Administration (HCFA) data show that less than 3 percent of all graft failures occur as a result of patient nonadherence to therapy for any reason (17).<sup>5</sup> Advocates argue that the HCFA data is

poorly coded (25,28). A National Kidney Foundation survey suggests that nonadherence to therapy may account for almost 10 percent of kidney graft losses after the frost year (25).

Thus, the extent to which impaired financial access leads to organ rejection is highly uncertain. Furthermore, perfect patient adherence to the prescribed protocol is in no way guaranteed even if Medicare's coverage is expanded. Some patients voluntarily stop immunosuppressive therapy because of their perceived poor quality of life (7). Nonetheless, it is likely that at least some of the costs associated with organ rejection (e.g., additional hospital admissions, return to dialysis for kidney graft failure patients, and other costs associated with rejection episodes) would be reduced with expanded Medicare coverage.

Despite the lack of precise data, tracing out a very simplistic hypothetical scenario is a useful exercise to explore the potential magnitude of savings. If, hypothetically, as many as 10 percent of all graft failures were caused by the patient's financial inability to adhere to the drug regimen, this would mean that beyond the frost year of a transplant, approximately 268 Medicare recipient renal graft failures per year would be associated with nonadherence.<sup>6</sup> In the case of patients with ESRD, increased graft failure results in more patients returning to dialysis, at an annual average cost to Medicare (including patient liabilities) of approximately \$19,000 per patient each year (17). Thus, under this hypothesis, a Medicare policy that eliminated all graft failures associated with nonadherence would have an offsetting program savings of roughly \$5 million per year. Under a hypothesis of fewer graft failures due to nonadherence, offsetting savings would be correspondingly lower (e.g., if 3 percent failed for this reason, eliminating all of these failures would save approximately \$1.5 million). Preventing hospitalizations due to acute organ rejection would result in some additional savings.

Another way to view the potential savings from averting graft failure is to examine the relative

<sup>4</sup>There are some potential problems with this figure. It is based on a survey of surgeons' opinions regarding the percentage of their patients who have financial difficulty, not a survey of the patients themselves. In addition, the analysis of this survey averaged all of the surgeon-reported percentages together, which results in an accurate aggregate percentage only if all surgeons have the same number of patients.

<sup>5</sup>Based on an assessment of kidney graft failure codes from the transplant followup forms for all transplant failures occurring during the calendar years 1985 through 1988. Of the 5,580 graft failures in which a failure code was submitted, 3.3 percent were due to poor patient compliance with immunosuppressive therapy (17).

<sup>6</sup>There were an average of 2,677 kidney graft failures per year from 1985 to 1988 (17).

benefits of successful transplantation. HCFA has found that transplants pay for themselves when compared with dialysis within 3.7 years for living-donor kidney patients and 4.7 years for cadaver-donor kidney patients (17).<sup>7</sup>

### ***Manufacturers' Incentives for Technological Developments***

Medicare coverage policy changes will probably have only a slight effect on overall level of use of outpatient immunosuppressive drugs. Thus, coverage policy changes will probably also have little effect on manufacturers' incentives to pursue technological developments. The main effect might be to remove any existing disincentive against developing new immunosuppressives that would be expensive on the market, since Medicare currently pays fairly generously for covered drugs.

Changes in payment policy for the drugs, on the other hand, could affect development incentives substantially. Studies have shown that industry is extremely sensitive to changes in method of payment in terms of pricing strategies and incentives for developing emerging technologies (51). The precise direction of the incentives would depend on the payment policy adopted.

### ***Other Program Costs Associated With Expanded Coverage***

If coverage were expanded past the current 1-year limit, Medicare outlays would increase due to the cost of the outpatient immunosuppressive drug. In addition, Medicare expenditures would result from any related increase in services provided by physicians and outpatient hospital facilities.

Furthermore, if coverage for drugs were expanded, Medicare might come under pressure to cover other outpatient services that are required by transplant recipients or other Medicare beneficiaries. For example, some transplant recipients require outpatient nonimmunosuppressive prescriptions to prevent development of secondary complications (e.g., hypertension, stomach ulcers, and bone disorders). Total program costs might increase if coverage were extended to include these drugs as well. Similarly, easing financial access to drugs for transplant recipients through measures such as reducing coinsurance obligations might lead other Medicare beneficiaries (e.g., dialysis patients) to argue that their coinsurance obligations should be reduced as well.

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<sup>7</sup>The costs in this comparison did not include immunosuppressive drug costs for transplant patients or costs of erythropoietin for dialysis.